EXHIBIT A

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Office of the Secretary Int'l Trade Commission

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August 19, 2005

The Honorable Marilyn Abbott
Secretary
U.S. International Trade Commission
500 E Street, S.W.
Washington D.C. 20436

Re: Inv. No. 337-TA-___
Certain Modified Vaccinia Ankara Viruses ("MVA") and Vaccines and Pharmaceutical Compositions Based Thereon

Dear Secretary Abbott:

Enclosed for filing on behalf of Bavarian Nordic A/S (Complainant), please find the following documents in support of Complainant's request that the Commission commence an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended. Please note that Confidential Exhibit 19 contains confidential business information. Pursuant to the Commission's Rules of Practice and Procedure, a request for confidential treatment of this document is concurrently transmitted along with this filing. Accordingly, Complainants submit the following:

1. An original and twelve (12) copies of the verified Complaint (an original and one (1) copy unbound, without tabs (Rules 201.08(d) and 210.8(a));
2. An original and six (6) copies of the confidential and non-confidential exhibits to the Complaint (an original and one (1) copy unbound, without tabs (Rules 201.6(c), 210.4(f)(3)(i), and 210.8(a));
3. One (1) additional copy of the Complaint and accompanying confidential and non-confidential exhibits for service upon the one proposed respondent (Rule 210.8(a)) (it is understood that service of the confidential exhibits will occur only once an administrative protective order has been issued and pursuant to its terms);
4. One (1) additional copy of the Complaint and accompanying non-confidential exhibits for service upon the United Kingdom (Rule 210.8(a));
5. A certified copy of United States Patent Nos. 6,761,893 ("the '893 patent") and 6,913,752 ("the '752 patent") and a legible copy for each in each copy of the exhibits (Rule 210.12(a)(9)(ii));

6. A certified copy of the assignment of the '893 and '752 patents and a legible copy for each in each copy of the exhibits (Rule 210.12(a)(9)(ii));
7. A certified copy and three (3) additional bates-stamped copies of the prosecution history of the '893 and '752 patents, each copy including the patent and technical references mentioned in the prosecution history (two of the copies of the '893 patent prosecution history are provided in electronic form) (Rule 210.12(c)(2)-(3)); and
8. A letter and certification pursuant to Commission Rules 201.6(b) and 210.5(d) requesting confidential treatment of Confidential Exhibit 19.

Thank you for your attention to this matter.

Respectfully submitted,

For.

Edward A. Pennington
Counsel to Complainants

Enclosures

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August 19, 2005

The Honorable Marilyn Abbott
Secretary
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500 E Street, S.W.
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Re: Inv. No. 337-TA-___
Certain Modified Vaccinia Ankara Viruses ("MVA") and Vaccines and Pharmaceutical Compositions Based Thereon

Dear Secretary Abbott:

Pursuant to Commission Rules 201.6(b) and 210.5(d), Complainant requests confidential treatment for the exhibit designated Confidential Exhibit 19.

The information in Exhibit 19 comprises confidential business information, including an identification of budget information and expenditures made with respect to Bavarian Nordic's partners. It also includes timing and expenditure information with respect to studies being conducted using Bavarian Nordic's patented and proprietary technologies. This information has commercial value to Bavarian Nordic and its disclosure would cause substantial competitive harm to Bavarian Nordic.

On the following page is the certification required by Rule 201.6(b).

Respectfully submitted,

Robert C. Bertin
Counsel to Complainants

Enclosures

I, Robert C. Bertin, certify under penalty of perjury that to the best of my knowledge, information that is substantially identical to the confidential business information identified on the first page of this letter is not available to the public.

Date: August 8, 2005

Robert C. Bertin

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C. 20436

In the Matter of Certain Modified Vaccinia Ankara ("MVA") Viruses and Vaccines and Pharmaceutical Compositions Based Thereon	Investigation No. 337-TA-_____

BAVARIAN NORDIC'S COMPLAINT
UNDER SECTION 337 OF THE TARIFF ACT OF 1930

Complainant:

Bavarian Nordic A/S
Bøgeskovvej 9
DK-3490 Kvistgård
Denmark
45 33 26 83 83

Proposed Respondents:

Acambis Plc
Peterhouse Technology Park
100 Fulbourne Road
Cambridge, CB1 9PT
United Kingdom

Counsel for Complainant:

Edward A. Pennington
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I. INTRODUCTION

1. Bavarian Nordic A/S ("Bavarian Nordic") files this Complaint for violation of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 ("Section 337"), based upon the unlawful importation into the United States, the sale for importation into the United States and/or the sale within the United States after importation of certain modified vaccinia Ankara ("MVA") viruses and vaccines and pharmaceutical compositions based thereon by proposed respondent Acambis Plc ("Acambis"). On information and belief, the accused MVA viruses and vaccines and pharmaceutical compositions based thereon infringe at least claims 1, 4, 5, and 34 of U.S. Patent No. 6,761,893 ("the '893 patent") and claims 1-9 and 13-16 of U.S. Patent No. 6,913,752 ("the '752 patent"). In addition to infringing the patented technology, the accused MVA viruses and vaccines and pharmaceutical compositions based thereon incorporate Bavarian Nordic's proprietary technology, including MVA strains and/or trade secrets, that was wrongfully obtained and/or used by Acambis, threatening to destroy or substantially injure the Domestic Industry defined in Section X below.

2. The products-at-issue in this investigation are MVA viruses and vaccines and pharmaceutical compositions based thereon that have in common an attenuated strain of MVA that cannot reproductively replicate in human cells. The vaccine product is a novel smallpox vaccine developed and pioneered by Bavarian Nordic to be less dangerous than traditional smallpox vaccines because it cannot reproductively replicate inside human cells. While it is intended to be used to vaccinate all individuals against smallpox, it is especially well suited for the vaccination of small children and immune-compromised persons. This vaccine is being imported by Acambis in furtherance of U.S.

government contracts for stockpiling and also by Acambis for other commercial purposes.

3. Bavarian Nordic seeks as relief an exclusion order barring from entry into the United States MVA viruses and vaccines and pharmaceutical compositions based thereon that infringe its '893 and '752 patents. In addition, Bavarian Nordic seeks as relief an exclusion order barring from entry into the United States MVA viruses and vaccines and pharmaceutical compositions based thereon that incorporate Bavarian Nordic's proprietary technology wrongfully obtained and/or used. Bavarian Nordic also seeks a cease and desist order prohibiting the importation, sale, offer for sale, advertising and/or the solicitation of the sale of certain MVA viruses and vaccines based thereon encompassed by Bavarian Nordic's patented and proprietary technologies.

II. THE PARTIES

A. Complainant

4. Bavarian Nordic is a Danish business entity based in Copenhagen, Denmark, which owns the '893 and '752 patents and other proprietary technology relating to MVA viruses and vaccines and pharmaceutical compositions based thereon. Bavarian Nordic has pioneered a new strain of MVA virus called MVA-BN®, which cannot replicate inside human cells. Therefore, it is one of the world's safest technologies for developing vaccines against diseases such as smallpox, HIV/AIDS and cancer. Bavarian Nordic's smallpox vaccine is called IMVAMUNE™.

5. Bavarian Nordic has two U.S. subsidiaries, Bavarian Nordic Inc. and BN ImmunoTherapeutics Inc., both of which are business entities incorporated under the laws of the State of Delaware. Bavarian Nordic Inc. has its principal place of business at

1209 Orange Street, Wilmington, DE 19801 and BN ImmunoTherapeutics Inc. has its principal place of business in Palo Alto, California.

6. Bavarian Nordic Inc. is a holding company for BN ImmunoTherapeutics Inc. and is a wholly owned subsidiary of Bavarian Nordic. BN ImmunoTherapeutics Inc. is also a subsidiary of Bavarian Nordic, but not one wholly owned. BN ImmunoTherapeutics Inc. is currently engaged in economic and technical development activity involving the use of MVA-BN®.

B. Proposed Respondent

7. On information and belief, Acambis Plc is a corporation existing under the laws of the United Kingdom with a registered address at Peterhouse Technology Park, 100 Fulbourn Road, Cambridge CB1 9PT, UK. The company secretary is Elizabeth Brown, also of Peterhouse Technology Park, 100 Fulbourn Road, Cambridge CB1 9PT, UK. Acambis Plc and/or its U.S. subsidiary Acambis Inc. (collectively "Acambis") have imported into the United States from Europe a MVA-based smallpox vaccine called MVA3000.

III. BACKGROUND ON THE PRODUCTS-AT-ISSUE AND PARTIES

A. Smallpox and Licensed Smallpox Vaccines

8. Smallpox is an acute contagious disease usually spread from person to person through close contact. One form of the disease, variola major, is highly virulent with a mortality rate of greater than 30 percent. While there is no specific treatment for smallpox, it can be prevented through vaccines.

9. The only smallpox vaccine currently approved by the U.S. Food and Drug Administration ("FDA") for innoculating the general population in the United States,

Dryvax®, is a live-virus preparation of vaccinia virus prepared from calf lymph. The calf lymph is purified, concentrated, and dried by a process called lyophilization. There are several other smallpox vaccines currently being evaluated in clinical investigations that are derived from the same virus strain as Dryvax®.

10. In general, infection of a patient with a virus in the form of a vaccine is done with the intention of conferring immunity to a disease. Generally, the virus is specially prepared and/or packaged for sale and/or use as a vaccine, for example by growing the virus under otherwise sterile conditions, drying the preparation to a powder form, and packaging the dried powder in a sterile, sealed container. Pharmaceutically acceptable carriers, diluents, and/or additives may be included at this point or may be added afterwards in preparation for administration of the virus/vaccine to a patient.

B. Bavarian Nordic's Breakthrough Vaccine

11. Bavarian Nordic is a world leader in the development and production of innovative vaccines and related products which prevent and treat infectious diseases.

12. Beginning in 1996, Bavarian Nordic sought to develop a new generation of smallpox vaccines that would be safer and more effective for individuals for whom the traditional smallpox vaccine is more dangerous, such as patients with disorders of the immune system or skin conditions such as eczema, or other disorders presenting a higher risk of complications from existing smallpox vaccines. Through an extensive, multi-million dollar research and development effort, Bavarian Nordic succeeded in developing such a smallpox vaccine based on Bavarian Nordic's core technology, MVA-BN®.

13. MVA-BN® is an attenuated[1] strain of modified vaccinia virus Ankara ("MVA") that cannot reproductively replicate[2] inside human cells. Therefore, MVA-BN® is one of the world's safest, multivalent vaccine vectors for the development of vaccines against smallpox, as well as HIV/AIDS, breast cancer, colon cancer, and prostate cancer. Several of Bavarian Nordic's vaccines are in Phase I and Phase II clinical trials.

14. A smallpox vaccine based on MVA-BN® is identified by its trademark "IMVAMUNE."

15. Bavarian Nordic owns several U.S. patents and pending patent applications directed to MVA-based vaccines. For example, U.S. Patent Nos. 6,761,893 and 6,913,752 cover, *inter alia*, the MVA-BN® virus and derivatives thereof, MVA-based smallpox vaccines, such as IMVAMUNE™, and the use of MVA-BN® as a vector.

16. There are ongoing contracts between Bavarian Nordic and the U.S. government to stockpile and test, through clinical trials, IMVAMUNE™. In recognition of its importance to the health and safety of the U.S. population, IMVAMUNE™ is the first smallpox vaccine candidate to be granted "fast track" status by the FDA for clinical development.

C. Acambis' Business

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[1] Generally, a virus strain is regarded as attenuated if it has lost its capacity or only has reduced capacity to reproductively replicate in host cells. *See, e.g.*, the '893 patent at Col. 1, lines 54 - 56 (Exhibit 1).

[2] A virus has an ability to reproductively replicate in cells that can vary from cell to cell. MVA-BN® is a virus capable of reproductive replication in chicken embryo fibroblasts, thus facilitating production of large amounts of the virus for vaccines. However, MVA-BN® is not capable of reproductive replication in human cells, and thus is relatively safe for use in a vaccine. *See generally* the '893 patent at Col. 2, lines 7 - 58.

17. Acambis develops vaccines to prevent and treat infectious diseases. According to their website (www. acambis.com), for example, Acambis holds the North American sales rights to the world's only licensed oral typhoid vaccine, Vivotif® (Typhoid Vaccine Live Oral Ty21a).

18. Upon information and belief, Acambis' entry into smallpox vaccine production and sale started in September 2000 when it received a contract from the U.S. government under which it supplies ACAM2000, which is a smallpox vaccine derived from the same vaccine strain as Dryvax®, *i.e.*, a live virus preparation of vaccinia virus prepared from calf lymph.

19. Upon information and belief, prior to the U.S. Government's release of a Request for Proposal for MVA-based smallpox vaccines in September 2002 ("First RFP"), all of Acambis' research and development efforts were focused on smallpox vaccines produced and sold under the tradenames ACAM1000 and ACAM2000. Upon information and belief, prior to the First RFP, Acambis did not actively research or produce a smallpox vaccine based on a weakened form of the MVA strain that would be safe for use in immunocompromised individuals, as well as for the general population.

20. Upon information and belief, Acambis has partnered with Baxter Healthcare Corporation ("Baxter") to develop a MVA-based smallpox vaccine under two U.S. Government contracts. Upon information and belief, Baxter manufactures in Europe, at least in substantial part, the MVA-based vaccine product MVA3000 (also known as ACAM3000) for shipment to Acambis and/or its customers in the U.S.

D. MVA Strains

21. All sources of MVA originate from Professor Anton Mayr.[3]

22. On or about May 28, 1996, Bavarian Nordic acquired the exclusive license from Professor Mayr for the commercialization of all MVA strains.

23. In January 1994, Professor Mayr deposited MVA-572 in the ECACC, *i.e.*, the European Collection of Animal Cell Cultures. MVA-572 is the isolate derived by Professor Mayr from specific passage number 572 of MVA through chicken embryo fibroblast cells.

24. The ECACC prohibits the commercialization of MVA-572, or any derivatives thereof, without express written consent of the individual or organization that submitted the virus. Other isolates of MVA, including MVA-575 (derived from specific passage number 575 of MVA through chicken embryo fibroblast cells), have also been deposited in the ECACC by either Professor Mayr or Bavarian Nordic.

25. Dr. Bernard Moss of the Division of Microbiology and Infectious Diseases ("DMID"), National Institute of Allergy and Infectious Diseases ("NIAID"), National Institutes of Health ("NIH"), requested a sample of MVA-575 from Professor Mayr in 1995. Professor Mayr subsequently provided Dr. Moss with MVA-575.

26. In 2001, Dr. Moss requested from Professor Mayr an isolate of MVA from an earlier passage. Professor Mayr again complied with the request, this time providing Dr. Moss with MVA-572.

27. Professor Mayr provided Dr. Moss with MVA-575 and MVA-572 on the basis that 1) Dr. Moss was planning to use the strains for expression vector work, 2) the

[3] Professor Mayr, through his pioneering work from about 1960 to 1974, succeeded in attenuating the dermal vaccinia strain Ankara (CVA) by over 500 continuous passages through primary chicken embryo fibroblast cells.

strains were being provided for research only and were not to be used for any commercial purpose without express permission from Professor Mayr, and 3) the strains would not be given by Dr. Moss to any other person or entity without permission from Professor Mayr. Furthermore, the strains were already deposited into the ECACC with protection against commercialization of the strains without express permission.

28. On at least one occasion, a company seeking MVA from NIH and/or NIAID was specifically referred to Professor Mayr for permission to receive a sample of MVA strain from NIH and/or NIAID.

E. Secrecy Agreements and Related Disclosures

29. Under a non-disclosure between the DMID NIAID NIH and Bavarian Nordic, Bavarian Nordic disclosed the technology for MVA-BN®, which involves plaque purifying MVA-572 in a manner that attenuates the virus such that it does not replicate in humans. This disclosure led to sponsorship by the NIAID of a pre-Investigational New Drug Application with Bavarian Nordic during 2002 for IMVAMUNE™.

30. Bavarian Nordic and Acambis entered into a Secrecy Agreement in February 2002, prior to the first RFP, in order to facilitate licensing negotiations between Bavarian Nordic and Acambis with regard to Bavarian Nordic's MVA-BN® technology.

31. Pursuant to this Agreement, Bavarian Nordic personnel explained the technology for MVA-BN® and IMVAMUNE™ to Acambis personnel at a meeting held at Acambis' offices in Boston on June 12, 2002. Thomas Monath, the Chief Scientific Officer of Acambis Plc and Vice President of Acambis, Inc. attended the meeting. The clinical data, dosing, and production conditions that were disclosed were the culmination of Bavarian Nordic's extensive research and development efforts dating back to 1996.

32. Following the June 12, 2002 meeting, Acambis requested a licensing proposal, which Bavarian Nordic promptly delivered. The parties negotiated the licensing terms until approximately September 2002. However, after the release of the First RFP, Acambis halted all discussions with Bavarian Nordic.

F. The First RFP

33. The terrorist attacks of September 11, 2001 in the United States and the anthrax attacks via the U.S. Postal Service resulted in concerns that smallpox could be used as a weapon of bioterrorism. In response, the U.S. government expressed an interest in stockpiling smallpox vaccines.

34. Shortly after September 11, 2001, Bavarian Nordic met independently with DMID NIAID NIH and Acambis under Non-disclosure and Secrecy agreements, respectively, to discuss Bavarian Nordic's innovative MVA-based vaccines.

35. After its meeting with Bavarian Nordic, NIAID NIH released the First RFP in September 2002. The First RFP outlined the requirements for an attenuated form of the smallpox vaccine virus based on MVA.

36. Both Bavarian Nordic and Professor Mayr attempted to prevent NIAID NIH from releasing MVA-572 to successful applicants under the First RFP on the ground that the virus was originally provided to Dr. Moss for research and not for commercialization into vaccine products.

37. NIAID awarded two, three-year contracts in February 2003 totaling up to $177 million for advanced development of MVA-based vaccines against smallpox. The contract amount was divided between Bavarian Nordic and Acambis.

38. Acambis received MVA-572 or its progeny after the contract award in

February 2003 from NIAID NIH. *See* April 9, 2003 letter from Acambis to Bavarian Nordic at Exhibit 7.

39. When the First RFP was published in September 2002, Bavarian Nordic had already demonstrated the efficacy in preclinical and clinical studies regarding IMVAMUNE™.

40. Prior to the First RFP, Acambis produced only ACAM1000 and ACAM2000, smallpox vaccines based on non-MVA strains. Upon information and belief, while Acambis was in possession of Bavarian Nordic's proprietary information regarding MVA-BN® and IMVAMUNE™ prior to the release of the First RFP, neither it nor its U.S. subsidiary possessed any other technology regarding MVA-based vaccines or the MVA virus. In fact, Acambis initiated Phase I clinical trials only in March 2004 on a version of the MVA-based vaccine, *i.e.*, MVA3000, well after the award of the contract related to the First RFP.

41. Bavarian Nordic was given no notice of Acambis' preparation for and entry into the bidding process for the First RFP, even though Acambis and Bavarian Nordic were negotiating the licensing of Bavarian Nordic's MVA-BN® and technology related to IMVAMUNE™, and even though Acambis had entered into a non-disclosure agreement with Bavarian Nordic pursuant to which it agreed to use confidential information for evaluation purposes and not for any other (*i.e.*, commercial) purpose.

42. At least as early as June of 2002, Bavarian Nordic had informed Acambis of Bavarian Nordic's exclusive license for the commercialization of all MVA strains.

IV. THE PRODUCTS-AT-ISSUE

43. The products-at-issue in this investigation are MVA viruses and vaccines

and other pharmaceutical compositions based thereon that have in common an attenuated strain of MVA that cannot reproductively replicate in human cells. The vaccine product is a novel smallpox vaccine developed and pioneered by Bavarian Nordic to be less dangerous than traditional smallpox vaccines because it cannot reproductively replicate inside human cells. While it is intended to be used to vaccinate all individuals against smallpox, it is especially well suited for the vaccination of small children and immune-compromised persons.

44. The MVA virus product is an element of the smallpox vaccine. However, it also may be used as the basis of vaccines against other diseases including, for example, cancer and HIV/AIDS.

45. The pharmaceutical composition product may be any pharmaceutically acceptable composition that includes the MVA virus. Examples include a powder that contains the MVA virus or an intermediate form of the vaccine.

V. THE PATENTS-AT-ISSUE

A. U.S. Patent No. 6,761,893 B2

46. Bavarian Nordic is the owner by assignment of U.S. Patent No. 6,761,893 B2, entitled "Modified Vaccinia Ankara Virus Variant" ("the '893 patent"). A certified copy of the '893 patent is attached to the original copy of this Complaint (and a copy for each required copy of the Complaint) as Exhibit 1. A certified copy and three additional copies of the prosecution history of the '893 patent, which includes the patents and technical references cited during prosecution, are attached as Appendix A.

47. The '893 patent issued on July 13, 2004, based on an application (Application No. 10/439,953) filed by inventors Paul Chaplin, Paul Howley, and

Christine Meisinger on May 16, 2003. This application is based on International Application No. PCT/EP01/13628 (published on May 30, 2002 as WO 02/042480), filed on November 22, 2001, claiming priority to Danish Application No. 2000 01764, filed November 23, 2000. The '893 patent is valid and enforceable.

48. The inventors were employees of Bavarian Nordic at the time the invention was made, and have assigned all rights in this invention and all patents related to it to Bavarian Nordic. A certified copy of the '893 patent assignment, as duly filed with the United States Patent and Trademark Office, is attached to the original copy of this Complaint (and legible copies for each required copy of the Complaint) as Exhibit 2. The '893 patent itself was issued to Bavarian Nordic as the (owner) assignee.

B. U.S. Patent No. 6,913,752 B2

49. Bavarian Nordic is the owner by assignment of U.S. Patent No. 6,913,752 B2, entitled "Modified Vaccinia Ankara Virus Variant" ("the '752 patent"). A certified copy of the '752 patent is attached to the original copy of this Complaint (and a copy for each required copy of the Complaint) as Exhibit 3. A certified copy and three additional copies of the prosecution history of the '752 patent, which includes the patents and technical references cited during prosecution, are attached as Appendix B.

50. The '752 patent issued on July 5, 2004, based on an application (Application No. 10/439,439) filed by inventors Paul Chaplin, Paul Howley, and Christine Meisinger on May 16, 2003. This application is based on International Application No. PCT/EP01/13628 (published on May 30, 2002 as WO 02/042480), filed on November 22, 2001, claiming priority to Danish Application No. 2000 01764, filed November 23, 2000. The '752 patent is valid and enforceable.

51. The inventors were employees of Bavarian Nordic at the time the invention was made, and have assigned all rights in this invention and all patents related to it to Bavarian Nordic. A certified copy of the '752 patent assignment, as duly filed with the United States Patent and Trademark Office, is attached to the original copy of this Complaint (and legible copies for each required copy of the Complaint) as Exhibit 4. The '752 patent itself was issued to Bavarian Nordic as the (owner) assignee.

C. Patent Applications

52. Bavarian Nordic has several pending U.S. Patent Applications that are related to the '893 and '752 patents and/or the subject matter of MVA-based vaccines. In the event that any of these applications issues during the pendency of this 337 investigation, this Complaint may be amended accordingly.

D. Foreign Counterparts

53. Bavarian Nordic has eighteen (18) foreign patent applications pending that correspond to '893 and '752 patents. A chart showing each foreign patent application, with an indication of its prosecution status, is attached hereto as Exhibit 5. Both the '893 and '752 patents are based on International Application No. PCT/EP01/13628 (published on May 30, 2002 as WO 02/042480, now expired), filed on November 22, 2001, claiming priority to Danish Application No. 2000 01764, filed November 23, 2000.

E. Licenses Under the Patents-At-Issue

54. Bavarian Nordic has not granted licenses to any third parties under the '893 and '752 patents.

F. Non-Technical Description of the Patented Technologies

55. The following non-technical descriptions of the '893 and '752 patents are

not intended in any way to limit the scope of the claims of the patents. The '893 and '752 patents generally describe a virus useful in vaccines or other medications, and the use of that virus in vaccines against diseases including smallpox, cancer and HIV/AIDS. The virus is a MVA-derived virus that cannot reproductively replicate in human cells and thus can be safely and effectively administered to all subjects, especially to children and immune-compromised individuals.

56. The asserted claims of the '893 patent are directed to a strain of MVA virus exhibiting certain replication and immunological characteristics. A representative sample of a strain exhibiting these characteristics is on deposit at the ECACC. In addition, the claims cover any derivatives of the strain, which includes viruses exhibiting essentially the same immunological and replication characteristics, but exhibiting differences in one or more parts of its genome. Moreover, the asserted claims cover the genome of the virus as well as use of the virus in a pharmaceutical composition or vaccine.

57. The asserted claims of the '752 patent are directed to an attenuated strain of MVA that cannot reproductively replicate in human cells, but is capable of reproductive replication in chicken embryo fibroblasts. Additional features can include properties such as non-replication in different animals including humans and the production of an immune response. In addition, the asserted claims cover the virus used in a pharmaceutical composition or vaccine.

VI. BAVARIAN NORDIC'S PROPRIETARY TECHNOLOGY

A. The '572 Strain and its Progeny

58. On or about May 28, 1996, Bavarian Nordic acquired the exclusive license

from Professor Mayr for the commercialization of all MVA strains, including MVA 572 and its progeny (including MVA 575 and MVA-BN®). Bavarian Nordic put NIAID NIH and Acambis on notice prior to the delivery of the MVA strain to Acambis that it has the sole and exclusive right to commercialize MVA virus strains and that any other uses are wrongful and violate Bavarian Nordic's rights.

B. Proprietary Trade Secret Information

59. The effective dose and production/commercialization process for IMVAMUNE™ and the plaque purification and attenuation processes relating to MVA-BN® have been valuable proprietary property and trade secrets of Bavarian Nordic. *See* Declaration of Paul Chaplin, Exhibit 6.

60. Bavarian Nordic's proprietary technology has derived independent value from not being generally known to the public, or to other persons such as Acambis, who can obtain value from the disclosure thereof or use. As a general matter, these secrets have provided Bavarian Nordic competitive advantages, which include realizing a return on investment for the time and money expended in arriving at a successful smallpox vaccine for use in immune-compromised individuals as well as for the general population.

61. BN has made and continues to make efforts that are reasonable under the circumstances to secure the secrecy of its proprietary production process by imposing secrecy obligations on its employees and imposing restrictions on access to the production operation, as well as by executing non-disclosure agreements with potential licensees or other parties prior to disclosure.

VII. UNLAWFUL AND UNFAIR ACTS OF THE RESPONDENT

A. Infringement of the '893 Patent

62. On information and belief, Acambis manufactures (or has manufactured) and imports (or has imported) into the United States, sells for importation into the United States and/or sells after importation into the United States viruses and vaccines and pharmaceutical compositions based on MVA, including the vaccine designated MVA3000, that infringe claims 1, 4, 5 and 34 of the '893 patent.

63. Attached to this Complaint as Exhibit 7 are publications and news releases from Acambis detailing its continuing use of MVA variants to produce a MVA-based smallpox vaccine identified as MVA3000. Exhibit 8, which includes relevant portions of Acambis' 2004 Annual Report, also demonstrates the continued use of Bavarian Nordic's patented and proprietary technology to produce an MVA-based smallpox vaccine identified as MVA3000. On information and belief, the accused viruses and vaccines and pharmaceutical compositions based on MVA, including MVA 3000, directly infringe claims 1, 4, 5 and 34 of the '893 patent as shown in the claim chart demonstrating infringement of these claims attached as Exhibit 9.

B. Infringement of the '752 Patent

64. On information and belief, Acambis manufactures (or has manufactured) and imports (or has imported) into the United States, sells for importation into the United States and/or sells after importation into the United States viruses and vaccines and pharmaceutical compositions based on MVA, including the vaccine designated MVA3000, that infringe at least claims 1-9 and 13-16 of the '752 patent.

65. Attached to this Complaint as Exhibit 7 are publications and news releases from Acambis detailing its continuing use of MVA variants to produce a MVA-based

smallpox vaccine identified as MVA3000. Exhibit 8, which includes relevant portions of Acambis' 2004 Annual Report, also demonstrates the continued use of Bavarian Nordic's patented and proprietary technology to produce the MVA-based smallpox vaccine identified as MVA3000. On information and belief, the accused viruses, virus preparations and/or vaccines based on MVA, including MVA 3000, directly infringe at least claims 1-9 and 13-16 of the '752 patent as shown in the claim chart demonstrating infringement of these claims attached as Exhibit 10.

C. Misappropriation of Bavarian Nordic's Proprietary Technology

66. Upon information and belief, Acambis developed MVA3000 based upon MVA-572 or its progeny, and Bavarian Nordic's proprietary information, both of which are Bavarian Nordic's proprietary technology and neither of which Acambis had a right to use. Acambis unfairly competed with Bavarian Nordic by creating a vaccine, MVA3000, through its wrongful acquisition of MVA-572 or its progeny and its misappropriation of Bavarian Nordic's proprietary information relating to IMVAMUNE™ and MVA-BN®. The unfair competition extends to importation of MVA3000 from Europe into the United States to supply a vaccine stockpile for agencies of the U.S. Government and for other commercial purposes.

67. In particular, upon information and belief, Acambis had never been involved in the development of MVA-based vaccines before Bavarian Nordic shared its proprietary technology with Acambis. Acambis' prior lack of involvement in, or knowledge of, smallpox vaccines based on an attenuated strain of MVA, and the sudden entry of Acambis into direct competition with Bavarian Nordic for the First RFP, make clear that Acambis used the proprietary information it obtained from Bavarian Nordic

during the June 12, 2002 meeting and subsequent meetings thereto in order to make MVA3000. Acambis' recent initiation of clinical trials relating the MVA3000 make clear that any "research and development" of the MVA-based vaccine occurred only after the award of the first contract and the receipt of the necessary strain.

68. Acambis received MVA-572 or its progeny from the NIAID NIH after the First RFP was awarded and with knowledge that MVA-572 was Bavarian Nordic's property. To the extent that MVA-572 was plaque purified and/or attenuated by NIAID NIH prior to delivery to Acambis using Bavarian Nordic's proprietary technology relating to MVA-BN® and IMVAMUNE™, Acambis, as a third party receiver, misappropriated, and continues to misappropriate, Bavarian Nordic's proprietary technology by using the technology to make and/or supply for importation MVA3000 to its commercial advantage, without Bavarian Nordic's consent. Based on the June 12, 2002 meeting with Bavarian Nordic, Acambis was aware that Bavarian Nordic had invested substantial time and money to develop an attenuated MVA strain for use in smallpox vaccines. Based on this knowledge and knowledge of the smallpox vaccine industry, Acambis knew or should have had reason to know that any attenuated MVA strain received from NIAID NIH was provided to Acambis without express or implied consent from Bavarian Nordic.

69. To the extent that MVA-572 was plaque purified and/or attenuated by Acambis after receipt of the strain from NIAID NIH using Bavarian Nordic's proprietary technology relating to MVA-BN® and IMVAMUNE™, Acambis has modified a MVA virus that Acambis had no right to possess or exercise control over based on proprietary information and technology misappropriated from Bavarian Nordic. All such

modifications of MVA unlawfully in the possession of Acambis and such misuse of Bavarian Nordic's proprietary technology to Acambis' commercial advantage without Bavarian Nordic's consent constitutes misappropriation of trade secrets. Acambis knew or had reason to know that any plaque purification and/or attenuation of MVA-572 by them required adoption and use of Bavarian Nordic's MVA-BN® proprietary technology disclosed to them during the June 12, 2002 meeting. This proprietary technology was acquired by Acambis under circumstances giving rise to a duty to maintain secrecy and limit its use.

VIII. SPECIFIC INSTANCES OF IMPORTATION AND SALE

70. Bavarian Nordic and Acambis are contractors under NIH contracts for the development, testing, and production of a MVA smallpox vaccine. Exhibit 13 and Exhibit 14 support Bavarian Nordic's contention that Acambis is such a contractor under the contracts awarded from the First RFP and a subsequent (the "Second RFP"), attached hereto as Exhibit 15 and Exhibit 16, respectively.

71. Exhibit 15 contains the First RFP, *i.e.*, RFP No. NIH-NIAID-DMID-03-44, pursuant to which a contract was awarded to Acambis in February 2003. Exhibit 16 contains the Second RFP, *i.e.*, RFP No. NIH-NIAID-DMID-04-49, pursuant to which a contract was awarded to Acambis in September 2004. Based on the milestone requirements under the First and Second RFPs, and the contract award dates, Acambis has imported or will import MVA3000 doses into the United States from Europe according to the schedule below:

RFP	Milestone	#Doses	Required Date
First RFP	2	5000	August 2003

Second RFP	7	500,000	August 2005
Second RFP	14	3,000,000	September 2006

72. Upon information and belief, Acambis had to complete milestones, and therefore import doses of MVA3000 into the United States, under the First RFP in order to win a contract award pursuant to the Second RFP. With respect to milestones under the Second RFP, Acambis stated in a press release that it has "successfully completed all planned activities to date and [has] met every milestone and deadline since being awarded the NIAID contract in September 2004." *See* April 28, 2005 press release at Exhibit 7. Some of the doses imported pursuant to the milestone schedule above may be for clinical testing. However, the vast majority of doses were or are being imported for the purpose of stockpiling the vaccine.

73. Acambis has stated its intention to "market the vaccine for commercial sales as well as to the US government." *See* April 9, 2003 Letter from Acambis to Bavarian Nordic at Exhibit 7.

74. According to Acambis, it does not have the capacity in its Canton, MA facility to manufacture the required doses of MVA3000. Therefore Acambis has engaged Baxter to manufacture large quantities of MVA3000 in a plant in Europe for importation to the United States. *See* March 2, 2004 preliminary results conference call and the Final Transcript of ACAM-Q1 2005 Acambis Earnings Conference Call at Exhibit 7.

IX. RELATED LITIGATION

75. There has been no litigation to date related to the patented or proprietary technologies.

X. DOMESTIC INDUSTRY

A. Technical Prong

76. As required under 19 U.S.C. § 1337(a)(2), and as defined in § 1337(a)(3), a domestic industry exists or is being established in the United States relating to the articles and methods protected under the '893 and '752 patents and Bavarian Nordic's Proprietary Technology.

77. Bavarian Nordic's MVA-BN® virus and the smallpox vaccine IMVAMUNE™, which are each covered by at least one of the asserted claims of the '893 and '752 patents and which incorporate Bavarian Nordic's proprietary technology, have been imported into the United States pursuant to awards under the First and Second RFPs to Bavarian Nordic and for research and development activities unrelated to the RFPs. *See, e.g.*, Declaration of Paul Chaplin at Exhibit 6 and the claim charts at Exhibit 17. The general business of Bavarian Nordic is the development, production, and marketing of innovative vaccines to prevent and treat infectious diseases. Bavarian Nordic has development programs targeting HIV/AIDS and smallpox, as well as pre-clinical research programs addressing a number of infectious diseases.

B. Economic Prong

1. Investment in U.S. Facilities

78. Bavarian Nordic Inc. is a holding company for BN ImmunoTherapeutics Inc. and is a wholly owned subsidiary of Bavarian Nordic. BN ImmunoTherapeutics Inc. is also a subsidiary of Bavarian Nordic, but not one wholly owned. BN ImmunoTherapeutics Inc. is currently engaged in economic and technical development activity involving the use of MVA-BN®.

79. The facility of BN ImmunoTherapeutics in the Palo Alto area of California, specifically at 2425 Garcia Ave, Mountain View, CA 94043, is large and was intended to facilitate collaboration with nearby universities. BN ImmunoTherapeutics Inc. has ordered laboratory and office equipment to fill its facility and conduct research and development on present and future MVA-BN® products.

2. Significant Employment of Labor or Capital

80. Bavarian Nordic, through its U.S. subsidiaries, has initially invested approximately $4 million to fund research and preclinical and clinical development activities for MVA-BN® based vaccines primarily against breast, prostate and colon cancer and immune therapies in the U.S. Further funding is forthcoming. *See* Exhibit 18 (Copenhagen Stock Exchange Announcement 12/16/2004).

81. Bavarian Nordic also employs labor and capital in the U.S. to conduct pre-clinical and clinical trials in the U.S. related to the IMVAMUNE™ smallpox vaccine and MVA-BN®. **Confidential Exhibit 19** sets forth the capital expenditures and labor employment for these present and future tests and trials.

82. With respect to Bavarian Nordic's employment of labor and capital, Bavarian Nordic's investments related to MVA-BN® will be influenced strongly by the market forces surrounding the exploitation of MVA-BN®. In particular, the significant infringement of Bavarian Nordic's lawful patent rights and the consequent diminution of Bavarian Nordic's projected revenues caused by such infringement may have a negative impact on such investments.

3. Substantial Investment in the Exploitation of the Patented and Proprietary Technologies

83. Bavarian Nordic's patented and proprietary IMVAMUNE™ technology

has been used in research and development and production-related activities, such as: testing, quality control and inspection by Bavarian Nordic, its subcontractors, and subsidiaries, and the U.S. government in at least partial fulfillment of the requirements of the First and Second RFPs, and development activities unrelated to the RFPs. Moreover, the U.S. government has invested through the First and Second RFPs over $100 million in Bavarian Nordic's patented and proprietary MVA-BN® and IMVAMUNE™ technologies to test, prove and stockpile IMVAMUNE™ vaccine doses here in the United States.

84. Bavarian Nordic, through its U.S. subsidiaries, collaborates with several U.S. companies. In particular, Bavarian Nordic subcontracts with the following partners in the United States: Kendle International Inc., CentraLabs, and BCG. **Confidential Exhibit 19** also sets forth the capital expenditures and labor employment for these subcontracts.

XI. SUBSTANTIAL INJURY AND THREAT OF SUBSTANTIAL INJURY

85. The effect of Acambis' unfair practices described above has been to substantially injure and threaten substantial injury to the domestic industry that exists by virtue of Bavarian Nordic's investments and activities in the United States relating to Bavarian Nordic's proprietary technologies. Bavarian Nordic highlights below the indicia of substantial injury.

86. After obtaining Bavarian Nordic's proprietary technologies, Acambis solicited and continues to solicit business from Bavarian Nordic's main customer NIAID NIH based on the use thereof. As a result of its entry into the bidding process for First and Second RFPs, Acambis was successfully awarded two contracts. Bavarian Nordic

was the second successful bidder. For example, the total contract award of $177 million under the Second RFP was divided between Acambis and Bavarian Nordic. It is reasonable to assume that the Bavarian Nordic would have received the entire award but for Acambis' unfair acts.

87. Acambis received MVA-572 or its progeny after the contract award in February 2003 from NIH. Bavarian Nordic has a valid, property interest in MVA-572 and its progeny based on its exclusive license from Professor Mayr for the commercialization of all MVA strains. Bavarian Nordic has been harmed by Acambis' wrongful exercise of possession and control over MVA-572 or its progeny in denial of Bavarian Nordic's rights to the strain.

88. Acambis' award of the contract under First RFP caused Bavarian Nordic to lose its competitive edge in the United States. For example, on information and belief, prior to First RFP, Bavarian Nordic was the only player in the MVA-based smallpox vaccine market. On information and belief, without Bavarian Nordic's proprietary technology, use of patented technologies, and the MVA strain, Acambis would not have been able to successfully bid on the First RFP. As such, by Acambis' bid, Bavarian Nordic lost a substantial portion of the total contract award. Likewise, Acambis' award under the Second RFP caused Bavarian Nordic to lose to Acambis many millions of dollars allocated to the project.

89. By its partnership with Baxter, Acambis is expanding its production capacity to manufacture large quantities of MVA3000 vaccine doses for importation into the United States and stockpiling by the U.S. government, which will affect both future government purchases and the non-governmental commercial sales of competing

smallpox vaccines, including IMVAMUNE™. Bavarian Nordic suspects that Acambis will bid on subsequent RFPs related to the patented and proprietary technologies and continue to injure Bavarian Nordic.

90. In addition, should the MVA3000 vaccine become FDA approved in the United States, Acambis' sales of MVA3000 after importation will force Bavarian Nordic to lower its prices to compete with Acambis, thereby precluding Bavarian Nordic from recouping its substantial research and development costs relating to MVA-BN® and IMVAMUNE™.

XII. REQUEST FOR RELIEF

WHEREFORE, by reason of the foregoing, Bavarian Nordic requests that the United States International Trade Commission:

a) Institute an immediate investigation pursuant to Section 337(b)(1) of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, with respect to violations by Acambis of that section arising from the importation into the United States, the sale for importation, or the sale after importation into the United States of the accused products;

b) Set a target date of not more than 12 months;

c) Schedule and conduct a hearing pursuant to Section 337(c) for the purposes of receiving evidence and hearing argument concerning whether there has been a violation of Section 337, and following the hearing, to determine that there has been a violation of Section 337;

d) Issue a permanent exclusion order pursuant to Section 337(d) excluding from entry into the United States of certain MVA viruses and vaccines and

pharmaceutical compositions based thereon that were made or processed by a means covered by or infringing one or more claims of the '893 and '752 patents, or that were fabricated using Bavarian Nordic's proprietary technology;

e) Issue permanent cease and desist orders pursuant to 337(f) prohibiting Acambis, its affiliates, subsidiaries, successors, or assigns from importing, selling, or offering for sale in the United States certain MVA viruses and vaccines and pharmaceutical compositions based thereon that infringe, use, or disclose, one or more claims of the '893 and '752 patents or Bavarian Nordic's Proprietary Technology;

f) Issue an order instructing Acambis to turn over any articles that are found to infringe Bavarian Nordic's patented technology or misappropriate its proprietary technology imported by Acambis or any of its subsidiaries or affiliates; and

g) Grant all such other and further relief as the Commission deems just and proper based on the facts determined by the investigation and the authority of the Commission.

Respectfully submitted,

Date: August 19, 2005

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pharmaceutical compositions based thereon that were made or processed by a means covered by or infringing one or more claims of the '893 and '752 patents, or that were fabricated using Bavarian Nordic's proprietary technology;

e) Issue permanent cease and desist orders pursuant to 337(f) prohibiting Acambis, its affiliates, subsidiaries, successors, or assigns from importing, selling, or offering for sale in the United States certain MVA viruses and vaccines and pharmaceutical compositions based thereon that infringe, use, or disclose, one or more claims of the '893 and '752 patents or Bavarian Nordic's Proprietary Technology;

f) Issue an order instructing Acambis to turn over any articles that are found to infringe Bavarian Nordic's patented technology or misappropriate its proprietary technology imported by Acambis or any of its subsidiaries or affiliates; and

g) Grant all such other and further relief as the Commission deems just and proper based on the facts determined by the investigation and the authority of the Commission.

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